



# The F.D.A. & The Regulation of Human Organs

## Citation

Phillip Criswell, The F.D.A. & The Regulation of Human Organs (May 2010).

## Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:8965632>

## Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA>

## Share Your Story

The Harvard community has made this article openly available.  
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

**The F.D.A.**  
**&**  
**The Regulation of Human Organs**

Phillip J. Criswell  
Class of 2010  
May 7, 2010

This paper is submitted in satisfaction of the course requirement

## **Abstract**

This paper looks into the reasons why the Food and Drug Administration did not declare themselves as having regulatory power over human organs that would be used for medical purposes such as organ transplants and discusses why the FDA should take over this regulatory power and the various arguments that could be used towards taking over this power and the various possible benefits of having organs under the same regulatory control as all the other human material/parts being regulated for medical purposes.

# TABLE OF CONTENTS

<b><u>I. INTRODUCTION</u></b>	<b><u>1</u></b>
<b><u>II. FDA REGULATION OF ORGANS</u></b>	<b><u>3</u></b>
A. ORGANS AS DRUGS	4
B. ORGANS AS DEVICES	7
C. ORGANS AS BIOLOGICAL PRODUCTS	10
D. TYING THE THREE TOGETHER	13
E. THE PROGRESSION OF MEDICINE THROUGH TIME	16
<b><u>III. THE GOOD THAT CAN COME ABOUT</u></b>	<b><u>19</u></b>
<b><u>IV. MODEL FOR A NEW GOVERNMENT SYSTEM</u></b>	<b><u>24</u></b>
NATIONAL RECORDS DATABASE	24
POSTMORTEM ORGAN DONOR PROGRAM	26
LIVING DONOR PROGRAM	28
RESTRICTIONS ON THE DONOR PROGRAMS	29
MEDICAL ASSURANCE UNDER LIVING DONOR PROGRAM	31
LEGAL AUTHORITY BEHIND SYSTEM APPLICATION	34
<b><u>V. POSSIBLE ISSUES WITH MODEL SYSTEM</u></b>	<b><u>35</u></b>
POSSIBLE FEARS	36
RIGHT TO PRIVACY ISSUE	38
<b><u>VI. CONCLUSION</u></b>	<b><u>40</u></b>

## **I. INTRODUCTION**

As are many things that you come across in life the Food and Drug Administration (FDA) was created in order to serve a purpose, this purpose is to help protect the public health. This is done through the regulation of various materials and products used in and on the human body. In addition to things like food and cosmetics the FDA's regulatory power also stretches out to the medical arena thus allowing them to regulate not just over drugs and vaccines but also medical uses of actual elements of human and animal bodies.

Although the FDA has gone forth and accepted regulatory power in terms of certain aspects of the human body for medical purposes there is still more that they could and should do in this area. It is no question that we have come a good way in terms of medical advancements with vaccines and other medicines but it is obvious by the many different diseases and viruses that continue to plague mankind that we still have a way to go. Though there may still be a vast amount that can be done through non-synthetic chemicals and mixtures created within a lab, truthfully, some of the things that may prove to be the best answers and cures for the human body probably come from none other than the human body itself rather than a non organic chemical concoctions.

Although it may not always work the way we would like and it can sometimes only take effect over the course of generations the human body is an amazing structure of organisms, and has the capability to evolve and adapt to surroundings just like we have noted with many other species of animals. In fact the human body in itself is extremely complex and is technically still more advanced than our current scientific development. It is because of the vast array of possibilities that could possibly be addressed that the FDA

should expand their regulatory control as a step in the right direction towards the possible creation of programs and further research in order to help further humanity in realm of public health.

Although we do thankfully have medicines and vaccines to help us survive our bodies in general have become more tolerant towards certain things that once could kill us. Additionally, there are some things that at one point in time were not as harmful in our bodies as they are now, another result of gradual change/ adaptation of the human body. One example of this would be the consumption of raw meat, which can cause salmonella poisoning. Although eating raw meat now could actually be deadly, though some people can still eat things like steak tar tare, humans are omnivores and thus can, and for many do, eat meat. Whether one believes in evolution or creationism you cannot deny the fact that we did not always have the technology and knowledge that we have now and thus the way we cook food currently has probably not always been the case. In the past people were more than likely consuming a hefty amount of bacteria from undercooked food but because of the body's ability to "evolve" and build up an immune system people more than likely did not have the same reaction to eating undercooked or raw food that many people have now.

Although there are many things that could be done to help push us in the right direction towards furthering scientific development and public health, the first thing that needs to be done is make the current system we have as efficient as possible. In terms of the FDA this means finally filling in the missing gap in the regulatory power when it comes to materials from the human body.

## **II. FDA REGULATION OF ORGANS**

Although tissues fall under the realm of body elements that the FDA has taken regulatory power over when it comes to Organ Donation this is an area that FDA has left in the hands of another organization, The Health Resources and Services Administration, the federal agency that presides over health care services. Although the HRSA's main function has to do with health care, which does align with the issue of organs donation, there is one fundamental problem with the current setup.

As aforementioned it is the FDA not the HRSA that has regulatory power when it comes to tissues but not organs, this split seems to suggest that they are different enough from each other that it could actually make sense that two different agencies have regulatory power over them, but in reality organs are not things that are completely separate from body tissues. Human organs and body tissues are not just two groups of things that merely come from the same place, the human body, human organs are actually comprised of tissues and cells. Thus the separation of Organs from tissues causes a separation in the agency involved with the regulation of the individual parts and the agency which is involved with the regulation of what the separate parts are able to come together and form as a whole.

Under the Federal Food, Drug, and Cosmetic Act there are three routes that the FDA could try and take in order to argue that human organs undoubtedly fall under their regulatory powers. Since the Federal Food, Drug, and Cosmetic Act gives them regulatory power over drugs, devices, and biological products the introduction of a valid argument that human organs can technically be seen as falling under the definition of a Drug, Device, and/or Biological Product would give them the ability to regulate the use

of them in organ transplantations as well as the extraction and storage procedures involved with organ transplantation as well.

### ***A. ORGANS AS DRUGS***

Out of the various things that the FDA could use to declare their ability to regulate human organs and procedures used in organ transplants the general thought that the argument that this power could be gained through the FDA's ability to regulate drugs is one that on its face may sound ridiculous but in reality is not so much.

In the textbook "Food and Drug Law: Cases and Material" it is mentioned that one of the previous administration's interpretation of the term drug made it uncertain as to whether the term could include human organs or not. The interpretation they were referring to stated that "a drug... is a chemical or a combination of chemicals in liquid, paste, powder or other drug dosage form that is ingested, or instilled into body orifices, or rubbed or poured onto the body in order to achieve its intended medical purpose."<sup>1</sup> Under this interpretation of the term drug it does seem very understandable how there could be uncertainty towards whether the FDA had the power to regulate organs. In fact, it seems like any argument for regulatory power by the FDA would be a stretch, but an argument based on this interpretation is actually possible.

According to Merriam-Webster's dictionary the word instilled is defined as meaning both "to cause to enter drop by drop" and "to impart gradually."<sup>2</sup> Although the drop by drop wording does not seem as if it would not advance the argument for regulating human organs, the second definition, "to impart gradually", which appears to

---

<sup>1</sup> Peter Hutt, Food and Drug Law: Cases and Materials, 939 (Robert C. Clark ed., Foundation Press, 2007) (1980)

<sup>2</sup> Merriam Webster Online, *Instilled*, <http://www.merriam-webster.com/dictionary/instilled>



be the definition the FDA was using for the term, does seem to work. Since an organ transplant is not a five minute procedure in which the doctors just drop the organ into the body and it attaches to the body on its own like a parasite, but rather one where they have to individually connect all the tissues and blood vessels in order for it function within the recipients body this portion of the interpretation of the term drug easily engulfs organ transplants. The only real difficulty when dealing with this interpretation of the term drug comes from the beginning of the interpretation, where it confines drugs to chemicals or a combination of chemicals in liquid, paste, powder, or other drug dosage form. This sentence of the interpretation seems to pretty much knock out all possible arguments that a human organ could fall under the term drug. The first part of the sentence “ Chemical or chemical compound” is not that hard to come up with an argument for. The FDA could push the argument that technically everything in the world is basically comprised a different complex chemical compositions and thus human organs are comprised of a chemical combination. This statement is one which scientists have been making for a good deal of time; in fact you can actually look up the chemical compositions of some organs online. Although this part of the argument is not that hard the real challenge comes about when looking at the end of the sentence which states that the chemical or chemical compound must come in a “liquid, paste, powder, or other drug dosage form”<sup>3</sup>. The only way to possibly make human organs fit into this interpretation of drugs would be to somehow manage to argue that each human organ, these complex chemical compositions, as a whole comprise what can be seen as a dosage of the chemical compounds or organ; an argument that probably is even more confusing than it sounds on its face.

---

<sup>3</sup> Hutt, *Supra* note 1, at 939

Though one could try and force there way through an argument that under the aforementioned interpretation of the term drug human organs would apply and thus they could be regulated by the FDA under the power to regulate drugs given to them through the Food, Drug, and Cosmetic Act. This argument would be a very tricky one to make and does not seem like one that would really hold up if challenged.

Despite the fact that under the old interpretation of the term drug it seems as if human organs would not fit within the regulatory powers of the FDA this does not destroy the argument for regulatory power under their authority to regulate drugs. In 2007 the Food and Drug Administration released their latest amended definition for the term drug. This new definition seems to completely take away any uncertainty as to whether the FDA could regulate human organs based solely on their ability to regulate drugs under the Food, Drug and Cosmetic Act.

The 2007 definition of the term drug states that “the term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C) under the definition from drug given in § 201 it appears that organs would easily fit into the description of what can be counted as a drug for purposes of FDA regulation under the Food and Drug Act”<sup>4</sup>.

---

<sup>4</sup> 21 U.S.C. 321 § 201 (g)(1)

Since the human organs in a organ transplant are for the purpose of replacing the malfunctioning organ in the person's body it can easily be stated to be for the purpose of curing the transplant recipient of the illness that they have or at the very least as a treatment for it and thus would easily fall under §21 (g) (B). Additionally, since a diseased or malfunctioning organ is chemically different and than a healthy organ and acts different than a healthy functioning organ<sup>5</sup>, the transplant of a healthy human organ into someone's body can be stated to affect the function of the sickly persons body and would thus also fit under §201 (g) (C). Thus with the new definition of the term drug it appears that the FDA technically could take control of the regulatory power over human organs and organ transplants under their power to regulate drugs.

## ***B. ORGANS AS DEVICES***

When the original question of whether the FDA could regulate organs was being looked into the FDA definition of the term device seemed to pretty much bar them from taking regulatory control of human organs under that portion of their regulatory powers. The definition that was being used at the time for the term device was “ ‘an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article... which is... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease’ or which is

---

<sup>5</sup> According to the Institute of Liver Diseases of the General Hospital of Beijing Military Region liver diseases as well as certain nutritional situations change the chemical composition of a liver. Institute of Liver Diseases, *The chemical composition of the liver*, <http://www.ganbing.com.cn/YLW21.htm>

‘intended to affect the structure or any function of the body,’ and ‘which does not achieve any of its principal intended purposes through chemical action within or on the body’”<sup>6</sup>.

Although human organs could fit within the first part of the definition since organs used for an organ transplant could be stated to be an implant, since they are put into a body that was not the original body that the organ came from, that was for the purpose of curing the patient of the illness caused of having a diseased or bad organ in their body, the end of the definition, which states that the primary purpose cannot be obtained through chemical action within the body seems to go against use of the term to regulate human organs.

As stated within the “Food and Drug Law” text book it appears that the term was probably defined in a way that only man made or partially man made objects would be able to fit under this category. Although the text can be read to reject the argument that human organs cannot be regulated by the FDA under their power to regulate medical devices, based upon the text of the originally used definition this would not necessarily apply to all human organs.

Where as livers, whose main functions are to regulate the chemical levels within ones blood and to create and excrete bile to break down fats<sup>7</sup>, would be disqualified from being something that the FDA could regulate under the aforementioned definition of devices, hearts are organs that pump blood throughout the body, a process that is done as a result of electrical impulses. Therefore, unlike the Liver, which actually produces a product and thus serves its primary purpose through chemical action the heart is “ a

---

<sup>6</sup> Hutt, *Supra* note 1, at 940

<sup>7</sup> Lucile Packard Children’s Hospital at Stanford, *How the Liver Works*, <http://www.lpch.org/diseasehealthinfo/healthlibrary/digest/liverant.html>

muscular organ”<sup>8</sup> that continuously pumps blood throughout the rest of the circulatory system, which carries blood to the entire body. “An electrical system regulates your heart and uses electrical signals to contract the heart's walls. When the walls contract, blood is pumped into your circulatory system. A system of inlet and outlet valves in your heart chambers work to ensure that blood flows in the right direction.”<sup>9</sup>

Despite the fact that an argument could be made under the old definition of the term devices for the FDA to have regulatory power over human hearts, separating them from other organs that we use in organ transplants would have more than likely been a worse idea than the separation of organs in general from body tissues. Thus, it is very understandable why the FDA probably would have not even wanted to try and go that route.

Though today, after a few decades, many things have changed in the world including some of the definitions used by the FDA, the argument that they could include human organs is still at the same place that it was back when the discussion of the FDA’s possible authority first came into play. Currently, the amended definition for the term devices that the FDA is using states that a device is “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does

---

<sup>8</sup> National Heart Lung and Blood Institute Disease and Conditions Index, *How the Heart Works*, [http://www.nhlbi.nih.gov/health/dci/Diseases/hhw/hhw\\_what.html](http://www.nhlbi.nih.gov/health/dci/Diseases/hhw/hhw_what.html)

<sup>9</sup> *Id*

not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.”<sup>10</sup> Although the definition seems to have been expanded upon a little and is not technically the same definition as before, it still includes the statement about the primary intended purpose not being able to be achieved through chemical action with the body. Thus the chance that the argument that the FDA could regulate human organs in general under their ability to regulate medical devices does not seem like one that would truly hold.

### ***C. ORGANS AS BIOLOGICAL PRODUCTS***

The last of the three main arguments towards why the FDA should be able to take regulatory control over human organs for the purposes of organ transplants deals with the fact that human organs could be seen to fall under the category of biological-products/biologics.

The Public Health Services Act, which the FDA looked towards when thinking about their ability to regulate human organs, authorizes the licensure of “biological product” which the act states to include “any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.”<sup>11</sup> When looking at the general text of this Act the fact that it includes blood, blood products, or analogous products, seems to give the initial allude towards the

---

<sup>10</sup> 21 U.S.C. 321 § 201 (h)

<sup>11</sup> 42 U.S.C. 262 (i)

idea that that the concept of human organs being looked at as biological products is one that would work. Although based upon the text alone this seems to be an appropriate route to take in an FDA claim to regulatory power over human organs, the FDA actually decided in the past that the language of the document in fact did not give rise to this claim.

The decision of the FDA that the definition of biological products did not encompass human organs was based on a combination of the text of the definition and the legislative history of the 1970 amendment. According to Hutt's "Food and Drug Law" the FDA felt that a narrow interpretation of the term analogous should be read into the act. This was based upon the fact that in the 1970 amendment both the terms "blood" and "blood component or derivatives" were added to the act due to the fact that when the 1902 Act was first promulgated the process behind blood transfusions was not known but since then had been discovered and were no longer experimental treatments, where as organ transplants, on the other hand, were still experimental as a result the FDA felt that the term analogous products should not encompass them.<sup>12</sup> Additionally, the decision to not count human organs as analogous products to blood products seemed to be further backed by the fact that in 1984 Congress passed the National Organ Transplant Public Law 98 - 507.

Looking back on the whole situation with biological products it seems as if the FDA may have possibly read too much into things. Although organ transplants were still experimental procedures at the time the Public Health Services Act was enacted and congress did not specifically put organs into the list of possible licensures, this does not mean that they did not want them to fall into the biological product category. Although

---

<sup>12</sup> Hutt, *supra* note 1, at 940

the act listed things that were authorized for licensure no actual definition of biological products were given in it. The fact that the act did not set provide a term or definition for the category but rather gave an incomplete list seems to say that it was still open to be extended upon.<sup>13</sup> Since organ transplants were still experimental procedures it may have simply been better to leave them off the list but leave room for them to still fall into that category rather than put them on the list only to realize that organ transplants in fact were a bad idea.

As for the fact that not long after the Public Health Services Act was enacted congress also enacted the National Organ Transplant Pub L. 98-507 this does not seem to support the argument that congress meant for the FDA not to have regulatory power over human organs in terms of organ transplants either. In fact, when looking at the document the Public Law seems to lean more towards the exact opposite argument. When you read through Public Law 98 – 507 the over arching purpose of it appears to be leaning more so towards the creation of a task force for the purpose of research and gathering information in regards to organ donation rather than trying to set up another agency. In the Pub. L. it describes the role of the task force that is put in place and when reading these descriptions you come across the same types of words and phrases over and over again, things like: “conduct comprehensive examinations” and “Prepare the assessments”. Additionally the act explicitly states a date in which the task force is supposed to terminate.

The portion of the Public Law that addresses administration only does so to state that they are to maintain an administrative unit to do things such as “coordinate with the

---

<sup>13</sup> Although the language in the Public Health and Safety Act did not set a definition for biological products but rather gave authorization for licensure of certain things, the language used is now stated in 42 USCS § 262 (i) to be the FDA definition for biological product.



organ procurement activities ... conduct a program of public information to inform the public of the need for organ donations...provide technical assistance to organ procurement organizations receiving funds under the Organ Procurement and Transplantation Network” and “submit to congress an annual report of the status of organ donation and coordination services.”<sup>14</sup>

The way things got to be where they are today in terms of human organs seems like it is probably more of a result of the fact that the FDA could of and should have taken over the regulatory control of human organs to be used for organ transplants but failed to do so.

In the law there have been various cases in which the courts have allowed for the expansion of the reading of an act as times brought about new developments. Congresses addition of the term blood can arguably be said to show that Congress technically intended for the scope of this act to grow as new procedures that fell within the realm of the definition given for the category were fully developed. Thus, the fact that the PHS Acts 1970 Amendment did not include the term organs but rather just added blood and blood products still leaves an argument for the FDA to have regulatory power over human organs, an argument that would probably hold today.

#### ***D. TYING THE THREE TOGETHER***

Despite the fact that technically the argument for regulating human organs under the term devices does not seem to have much validity for any organs other than hearts, when looking at the aforementioned arguments/ routes that the FDA could take to lump in organs under their regulatory powers the basic fact that each one in it’s own way could

---

<sup>14</sup> National Organ Transplant, Pub. L. 98 - 507

technically give rise to some sort of organ regulation adds to the overall argument that the wrong agency has been regulating this matter.

Although initially the FDA did not want to regulate under any of these three terms because of the possible reach and the problems that that could possibly cause as a result<sup>15</sup>, today the FDA should go this route like they have done since the 1970's with human tissue and stem cells.

Tissue transplants and tissue banks were originally things that the FDA did not regulate but over the course of time as the methods and procedures advanced and the demand rose this changed. As tissue banks became an independent industry the FDA felt a need for regulation.<sup>16</sup> Although nearly two decades past between the time when the FDA began contemplating regulation and the 1993 interim final rule that they published “requiring the screening and testing of tissue donors for certain transmissible diseases such as HIV and hepatitis, as well as the screening of donors for behavioral risk factors”<sup>17</sup>, in the end they did assert regulatory control over it.

The FDA should do the same thing they did with human tissue to human organs and take over the regulatory control under both their ability to regulate the approval of biologics as stated in the Public Health and Service Act and through its power under the Federal Food and Drug Cosmetics Act to regulate drugs. This route towards regulating human organs would be the same as how the FDA claims authority to regulate most other biologics.<sup>18</sup>

---

<sup>15</sup> Hutt, *supra* note 1, at 944

<sup>16</sup> Hutt, *supra* note 1, at 942

<sup>17</sup> New York Organ Donor Network, *The History of Tissue Transplantation*, [http://www.donatelifeny.org/transplant/tissue\\_history.html](http://www.donatelifeny.org/transplant/tissue_history.html)

<sup>18</sup> “FDA's regulatory authority for the approval of biologics resides in the Public Health Service Act (PHS). However, biologics are also subject to regulation under the Federal Food, Drug, and

According to the FDA website “Biological products can be composed of sugars, proteins, or nucleic acids, or a combination of these substances. They may also be living entities, such as cells and tissues. Biologics are made from a variety of natural resources—human, animal, and microorganism—and may be produced by biotechnology methods.”<sup>19</sup> As shown by the FDA’s description of Biologics the FDA already regulates numerous biological products that come from the human body . The FDA’s Center for Biologics Evaluation and Research (CBER) regulates “blood and blood components”, “gene therapy products”<sup>20</sup>, and “human tissue and cellular products used in transplantation”; and the Center for Drug Evaluation and Research (CDER), also found within the FDA, regulates biological products such as “monoclonal antibodies designed as targeted therapies in cancer and other disease cytokines (types of proteins involved in immune response)”, “growth factors (proteins that affect the growth of a cell)”, “enzymes (types of proteins that speed up biochemical reactions), such as thrombolytics (used to dissolve blood clots)” and “immunomodulators (agents that affect immune response).”<sup>21</sup> Although the biologics listed that the CDER regulates are biological products that they generally produce through the use of biotechnology, they are still biologics that technically originated from the human body. Based on the FDA description of Biologics, as well as the fact that tissues and cells fall under this category, human organs should fall into this category as well.

---

Cosmetic Act (FD&C Act) because most biological products also meet the definition of "drugs" cited within this Act.” U.S. Food and Drug Administration, *FDA 101: Regulating Biological Products*, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048341.htm>

<sup>19</sup> U.S. Food and Drug Administration, *FDA 101: Regulating Biological Products*,

<sup>20</sup> “FDA defines gene therapy products as products containing genetic material administered to modify or manipulate the expression of genetic material to alter the biological properties of living cells” U.S. Pharmacopeia, *Definition of Terms: Gene Therapy*, [http://www.pharmacopeia.cn/v29240/usp29nf24s0\\_c1046s118.html](http://www.pharmacopeia.cn/v29240/usp29nf24s0_c1046s118.html)

<sup>21</sup> FDA 101, *supra* note 19

## ***E. THE PROGRESSION OF MEDICINE THROUGH TIME***

As aforementioned in Section II (D) of this paper some of the biological products that the FDA regulates are human based products developed in laboratories. Although one may think that the fact these specific products are not all taken directly from a human but rather created by scientists that the FDA's ability to regulate them should not have any bearing on whether or not the FDA should be able to take regulatory control over human organs that are to be used for organ transplants, the FDA's regulatory power over them actually adds to the argument.

As time progresses so does science. Every day scientists are working towards more and more technological advances. One specific goal that scientists have been working towards is the ability to grow organs. This ability would drastically reduce or eliminate the need for people to donate organs to save the lives of those with malfunctioning ones. Although it may seem as if the ability to grow organs is a long way away the truth of the matter is that it has already begun. Over the last decade there have been successes when it comes to growing organs. In 2006 North Carolina a group of scientists lead by Dr.'s Anthony Atala, the "director of the Institute of Regenerative Medicine at Wake Forest University Baptist Medical Center", and Alan Retik, the "chief of urology at the Children's Hospital in Boston" succeeded in growing human bladders to be transplanted into seven different patients.<sup>22</sup>

---

<sup>22</sup> Logan Ward, Popular Mechanics, *Beyond Transplants: Growing Organs in the Lab*, <http://www.popularmechanics.com/science/4212851>

The patients in Dr. Atkas' study were all suffering from a disease called spina bifida, "a congenital birth defect that stunts brain and spinal cord development"<sup>23</sup> that is "caused by the incomplete closure of the embryonic neural tube."<sup>24</sup> One of the various affects of this disease is that it can put individuals at risk for kidney damage and can result in problems with urinary control.<sup>25</sup> Generally the procedure for treating patients with this diseased bladders involves surgeons taking some of a patient's own intestinal tissue and using it to repair the bladder but this treat is stated to lead to complication and can even cause cancer.<sup>26</sup> "In the new procedure, doctors extract muscle and bladder cells from a small piece of the patient's own bladder. The cells are grown in a Petri dish, then layered onto a three-dimensional mold shaped like a bladder. In a few weeks, the cells produce a new bladder, which is implanted into the patient. Within a few more weeks, the new bladder has grown to normal size and has started functioning."<sup>27</sup> After the bladder is functional it can be transplanted into the patient. Additionally, "Because the bladders are grown from a patient's own cells, there is no risk of rejection, as in a traditional transplant."<sup>28</sup>

The 2006 case in which Dr. Atala grew human bladders is just one case of growing human organs. In fact, Dr. Atala and the Wake Forest Institute for Regenerative Medicine are working on growing "22 different tissues and organs including things such as the heart, liver, kidney, pancreas, and wind pipes." Additionally, in a 2009 interview

---

<sup>23</sup> Haddam Neck, CNN, *Doctors grow organs from patients' own cells: Seven living with bladders from new process*,

[http://www.ivanhoe.com/channels/p\\_channelstory.cfm?storyid=22770](http://www.ivanhoe.com/channels/p_channelstory.cfm?storyid=22770)

<sup>24</sup> Wikipedia, *Spina Bifida*, [http://en.wikipedia.org/wiki/Spina\\_bifida#Signs\\_and\\_symptoms](http://en.wikipedia.org/wiki/Spina_bifida#Signs_and_symptoms)

<sup>25</sup> Neck, *supra* note 23

<sup>26</sup> Ward, *supra* note 22

<sup>27</sup> Neck, *supra* note 23

<sup>28</sup> Neck, *supra* note 23

Dr. Atala stated that the next trial that the Wake Forest Institute is going to undergo will be the growth of skin<sup>29</sup>, which is technically an organ.<sup>30</sup> Dr. Atala states that one of the procedures that they are “using to make skin involves actually taking a skin graft and then placing it in a bioreactor, and then allowing it to grow in the bioreactor,<sup>31</sup> making larger sheets.”<sup>32</sup>

With science rapidly advancing to the point in which tissues and cells can be taken and used to grow organs to be used for organ transplants the need to consolidate the regulatory power in regards to regulating the use of components of the human body that are used for medical purposes grows greater. Having a split in the agencies with regulatory power could create havoc in terms of trying to continue to move forward and could stunt scientific and medical advancement. This fact, that the split in regulatory powers can be burdensome, is one that has been admitted to by the agencies themselves in past final rule. In the 2007 joint ruling issued by them, which stated that blood vessels extracted with organs for organ transplant purposes would solely be under the regulation of the HRSA, the two agencies state in that the summary that the purpose for this is that “this change will eliminate the burden resulting from an organ procurement organization's efforts to comply with both FDA and HRSA rules with respect to blood vessels (FDA jurisdiction) and organs (HRSA jurisdiction).”<sup>33</sup>

As science continues to advance the problem that was brought up by the agencies in this final rule, as well as final rules in the past, will continue to arise. Therefore in

---

<sup>29</sup> Medical Breakthroughs, *New Generation of Healing: Growing New Body Parts – In – Depth Doctor’s Interview*, [http://www.ivanhoe.com/channels/p\\_channelstory.cfm?storyid=22770](http://www.ivanhoe.com/channels/p_channelstory.cfm?storyid=22770)

<sup>30</sup> “Weighing about 6 pounds, the skin is the body's largest organ.” MedicineNet.com, *Definition of Skin*, <http://www.medterms.com/script/main/art.asp?articlekey=7901>

<sup>31</sup> “A device that simulates the conditions of the human body.” New Generation, *supra* note 29

<sup>32</sup> New Generation, *supra* note 29

<sup>33</sup> HSRA 42 CFR 121

order to help ensure efficiency and help promote the continuous advancement of medical treatments and technology jurisdiction over the regulatory power of human organs should lie in the hands of the FDA so that the same agency has regulatory control over the medical use of stem cells, blood, blood products, tissues, organs, and the biological devices that are used in the storage and the in vitro generation of the human body products.<sup>34</sup>

### **III. THE GOOD THAT CAN COME ABOUT**

There are various reasons as to why it would be better for the Food and Drug Administration to have regulatory control over the use of human organs for medical/transplant purposes. First there is the fact that by compiling everything under the regulatory power of the FDA we would sidestep any future agency squabbles over who has regulatory control over what, if ever, any new medical information were to come to light. Considering the fact that tissues and cells, both of which are under the regulatory control of the FDA, are now being used to successfully grow organs this is something that is very important. As more and more organs are grown rather than just simply extracted from a living or deceased donor, the likelihood of agency clashes will increase. Additionally the consolidation of all human parts that are used for medical purposes under the FDA would help reduce possible confusion amongst scientists and thus that may be caused by the fact that they are currently being regulated by two different agencies.

---

<sup>34</sup> “[S]ome medical devices used to produce biologics are regulated by CBER under the FD&C Act’s Medical Device Amendments of 1976” FDA 101, *supra* note 19

An overall lack of confusion and agency clashes could also help lead towards further advancements towards the regulation of human organs and biological materials from human bodies in general and possibly even the development of a new system in which we go about collecting cell and tissue samples as well as organ donor information which people would actually be willing to partake in.

In “ 1993, FDA issued an ‘Interim Rule for Human Tissue for Transplantation’ (58 FR 65514) which required donor screening, infectious disease testing, and record keeping to prevent the transmission of infectious diseases through human tissue used in transplantation. The regulation applied to ‘conventional’ human transplanted tissues (musculoskeletal, skin, ocular) but did not encompass tissue used in cellular therapies. Additionally, the regulation excluded semen and other reproductive tissue, human milk, bone marrow, and vascularized human organs, such as heart, kidney, liver, lung and pancreas.”<sup>35</sup> Although testing organs that are to be transplanted in the same way that the FDA’s rule required the testing of tissues would not really be a feasible idea due to the time it takes to test for diseases in relation to the need for organs and the short time span which many organs are able to be stored and still be transplanted into someone without any serious detriments or complications, if the FDA had regulatory control over organs the information taken from the testing of the different tissues could have been used to gain knowledge on whether the possible organs that someone donated might possibly be bad. For example, if someone is an organ donor and had previously donated tissue samples, if the tissue samples were tested and found to have a disease such as H.I.V. then this information would be put into the records of the tissue sample results and if

---

<sup>35</sup> U.S. Department of Health and Human Services, *U.S. Food and Drug Administration: Human Tissue Banking*, <http://www.fda.gov/NewsEvents/Testimony/ucm115217.htm>



something fatal were to happen to the person they Doctors would not need to even attempt to remove the organs from the body because they would be red flagged to show that this organ donor had a fatal disease that would infect the transplant recipient.

If a system was in place in which the results of the tests of all the people who donated blood, cord blood, bone marrow, tissue, etc. were kept in a registry as to eliminate people with certain illnesses that would be transferred in a transplant then that would help cut down on the possible risks of getting a transplant. Although there is always the possibility that someone contracted something since they last donated the ability to rule people out without having to test them on the spot for diseases could make the system more effective because some people would not need to be retested because they would already be ruled out from donating to a healthy person.

Although there are procedures in place to help prevent the transmission of diseases through organ transplants they still do not effectively provide safeguards against all infectious disease. With both new diseases and new strands of older diseases infecting people it is important to have some sort of system to help make things more efficient. For example, in order to try and prevent the spread of diseases such as H1N1 “the United Network for Organ Sharing, the nonprofit that operates the nation's organ-transplant system, recommended that lungs and intestines from donors known to be infected with the H1N1 swine-flu virus not be used because of infectious risk, and said the lungs of donors with seasonal influenza should also be avoided.”<sup>36</sup> With the number of organs that are being extracted from the corpses of organ donors to be transplanted into patients a great deal of time and money will be spent trying to test for these additional things when

---

<sup>36</sup> Laura Landron, The Wall Street Journal, *A Downside of Organ Donation*, (December 23, 2009) <http://online.wsj.com/article/SB10001424052748703344704574609960519672346.html>

some of it could have been saved by the mere creation of a database in which organ donor health information was kept. If there was one central database storing such vital information people who were treated for either H1N1 or seasonal influenza could be red flagged right away.

This fear that even today with our technological capabilities that we might still transmit diseases through organ transplants is one that is shared by numerous groups. According to the Wall Street Journal “In a new report commissioned by the U.S. Department of Health and Human Services, experts from the CDC and other government agencies warn that a patchwork of regulations and voluntary efforts by groups such as Unos aren't sufficient. The report, ‘Biovigilance in the United States: Efforts to Bridge a Critical Gap in Patient Safety and Donor Health,’ calls for the creation of a centralized system to monitor blood, organ and tissue safety, gather reports of illness or adverse reactions among recipients, and quickly trace organs and tissues from donors who are found to carry infectious diseases.”<sup>37</sup>

With living organ and tissue donors there is generally more time to do extensive testing to help ensure that the donor will not be passing on some sort of disease to the recipients but since the turn around for the transplantation of organs and tissues from deceased donors is shortened by the fact that the donor is dead and thus the organ and tissues must be extracted right away the ability to easily look up the donors information from their latest blood donation and also the ability to track every person that receives anything from the donor, whether it be tissue or an organ, would allow to help prevent the spread of disease. And even if by chance the deceased donor turns out to have had a

---

<sup>37</sup> *Id*

disease that could spread to the recipients of the transplants by having the information on both organ and tissue recipients easily accessible once one person is found to have gotten something from the transplant than the rest of the recipients can be checked immediately and if they have not contracted it than maybe something could be done to ensure that they do not get sick as well.

For example if tissue and organs are extracted from a corpse and are used for grafts, liver, heart, kidney, lung, and intestine transplants and then it is found that this person had cancer that had not been previously detected and that this could spread throughout the people that received the transplants they could possibly start the patients on treatment early on so that it does not costs them their lives or if possible give them a new organ transplant so that they will receive what is hopefully a healthy organ this time.

Due to the way things have been handled in the past it is somewhat understandable that a unified system of record keeping was never enacted. Unfortunately, there have been many cases in which use of such a system would have helped. One particular case is that in which a total of 91 different tissues and organs were extracted from deceased male donor who while he was living had a history of alcohol abuse. Although the donor had initially tested negative for hepatitis C it was later found out that he in fact did have the virus. Over a two year period forty different patients received transplants originated from the donor, some of which happened after it was discovered that he had in fact been carrying the Hepatitis C virus but because there was no system in place to keep track of things and allow them to notify the tissue banks that distributed the man's tissues, people who could have avoided receiving the diseased tissues wound up

getting them transplanted into them. Out of the recipients who received the diseased parts eight became infected with the virus, two of which died.<sup>38</sup>

“In the scramble to match sick patients with organs, time is often short, increasing the potential for missing a potentially transmissible disease. While organ donors are screened for certain diseases, such as hepatitis C and HIV, screening tests are costly and imperfect and don't cover every infectious disease.”<sup>39</sup> Because of this it seems important that we take every precaution that we can in order to help make transplants as safe for the recipients as we possibly can. Just one single diseased donor, if not caught in time, can have a negative reach on the lives and health of over a hundred individuals spread out across the world.

## **IV. MODEL FOR A NEW GOVERNMENT SYSTEM**

### ***NATIONAL RECORDS DATABASE***

The best thing to do would be to start things off from the moment an individual is born. When children are first born in order to help ensure that the child can be provided with effective treatment in the off chance that they get sick as a child, cord blood can be taken, tested, and stored. Since cord blood can be affectively stored for at least 10 years this would help ensure that if the child got sick within the first decade of their life there would be a sample of their own cord blood, which holds stem cells, that doctors can try and use to help regenerate any organ or tissue that may be diseased or deteriorating. Additionally, if needed it could be used to help grow new organs to be transplanted into

---

<sup>38</sup> *Id*

<sup>39</sup> *Id*

the child if the procedures for growing that particular organ or tissue have been somewhat perfected.

In addition to storing the cord blood a sample could also be tested to see if the child has any infectious diseases to start off with, something that is already done with babies anyway. The data from the tests of the baby's blood could serve as the first record in the child's national medical file which would be used later on in life if the child ever wanted to donate blood, organs, or tissues.

In addition to recording information to babies when they are first born, data should be recorded from school age children as well. Since in most places school children are required to give blood samples in order to go to school these samples can also be used to add to the child's file to see if there are any medical changes that should be taken note of. The process of using the results of a persons blood tests to add to their record any information that may be vital later on should continue every time someone receives a blood test. Additionally, all major illnesses that can cause a potential problem with a person's organs or tissue should be recorded in the database as well. By recording all vital information as it is received there will be background information to red flag people who decide to become organ donors or whose families decide to donate the persons organs after their death that may potentially cause illness in the transplant recipient. In order to help ensure that everyone's information is being allocated to the right file a finger print should taken from all patients the first time they are entered into the system and each time after that that they have tests done their finger print should either be scanned in or taken manually and sent off to be added into the persons file.

Maintenance of the National Record Database would not stop with individual health profiles but would also maintain information about all organ, tissue, blood, and cell donations and transplants made. All material extracted from an individual, either living or deceased, for the purpose of transplantation into another individual or to be used in the growth of tissues or organs will be given an identification number and tracked.

Since all individuals living within the country that have seen a doctor will have a record and identification number extracted materials are to be labeled by the persons identification number and the term for the item extracted from the donor. For tissues, the exact number of a tissue extracted shall be taken account of as well.

All hospitals and or tissue, cell, or blood banks must maintain records of all donations/samples that come through them and where they are distributed to. Even in instances in which an organ is extracted from a donor and then transplanted into someone within the same facility within a short period of time the information is to be thoroughly tracked and then entered into the system.

If an individual who was deemed healthy and free of any infectious diseases turns out to have been misdiagnosed than all transplants done from extractions from that individual can tracked and individuals can be tested for the disease and treated early on if the disease was contracted. Individuals who receive a transplant would have this information marked on their individual file as well along with the tracking information for all tissues and organs transplanted into their body as well as blood transfusions.

### ***POSTMORTEM ORGAN DONOR PROGRAM***

In addition to the general national database in which records on people's health are kept a government sponsored post mortem organ/tissue donor program could be

implemented as well. Although some of the hospitals and tissue banks involved in this could be privately owned the information would be sent into the database in order to allow the program to run properly. As a part of the program, people who sign up to be organ donors could be paid a small amount of money every six months if they decide to continue to be in the program and are eligible to stay in it. Although the participants of the donor program would have information in their files on their health already from any tests they may have had done at the doctors, one of the requirements of the program would be that the person is tested every six – seven months to ensure that they are not carrying certain diseases. Although the tests done on participants would be more than what someone would have done at a regular check up the fact that people are getting paid to participate in the program would probably diffuse most participants negative feelings towards the additional tests. Additionally, the fact that participants would have to get a check up and tests every six – seven months will help promote public health.

If someone decides not to participate in the program but rather just to simply sign the back of their drivers license one day, if anything were to happen to them the person's organs would still be extracted but if available any organs received from a program participant would be tested and transplanted before the organ from a non program member because the risk level of transferring a disease would be lower due to the various tests for diseases that the participant would have been required to have done.

In order to tell apart people who are and are not a part of the program participants should get a special card to carry alongside their driver's license indicating that they are in fact a member of the program. Additionally, participant's national health records should also indicate that the person is a current participant in the program. This way if

something should happen to someone who is not carrying their card a scan of the person's finger print could be used to identify whether or not they were a member of the program or not.

### ***LIVING DONOR PROGRAM***

In addition to the postmortem organ/tissue donor program, the government could also set up a living donor program as well. Like with the postmortem program the participants with the living donor program would be required to go through testing to ensure that they are eligible to donate but participants in this program would not receive payment for donating. Although where as the postmortem program would be put in place to help get people to become organ donors so that in the event of their death they would be able to help sick people in need of an organ, the living donor program would be designed more so to help people who have sickly relatives or friend and would like to donate organs to them.

Since the participants in this program would be alive when they donate, the rules for donating through this program would be more stringent than that of the postmortem program in that only certain organs, portions of organs, and tissues would be allowed to be donated. For example, a person with two working kidneys could donate a kidney but only one, and a person who had not donated a portion of their liver in the past seven years could donate a portion of that, but unless a person received a heart transplant with a heart that their body was rejecting and they had another one ready for transplant, no one would be eligible to donate their heart to someone else through this program.

In addition to the rules regarding what organs could be donated through the living donor program, participants should be required to undergo a psychological evaluation to



help ensure they are donating their organ for the right reasons and that they are psychologically stable enough to go through with the procedure.

Although there would be no financial compensation for participants of this program, in order to get more people to become living donors the program could provide the donors with medical protection in case their decision to donate their organ or body tissue resulted in them becoming ill late down the line. Since one of the things that can dissuade people from becoming an organ donor is the thought that they may one day need that organ or portion of an organ they donated, or that the surgery may result in the them getting sick, providing a protection to donors in case these events happen would remove some of the stress from their decision making process.

### ***RESTRICTIONS ON THE DONOR PROGRAMS***

Although the creation of a new system could drastically reduce the time on a transplant waiting list to the point in which it does not matter that much who gets which set of organs under no circumstances should the organs of a deceased/ cadaver , who while alive chose to be an organ donor, go to someone other than the next person in line on the list. Although an argument could be made that the family should have a say in the recipient at times, just in case someone within the immediate family is in need of the organ, this would not be a good idea. The reason for this is that the whole point of this system is to help more people live but allowing for the families to choose or even the person to make a pre death written decision about this matter completely goes against the goal of the program because it could/ and most likely would result in people sacrificing/ killing themselves in order to provide a crucial organ to someone they love rather than trying to wait on the list for an organ transplant.

Additionally, no living donor should be paid for donating an organ. Although the offering of a monetary payment in exchange for donating an organ could possibly help increase the number of people willing to donate a kidney or a portion of their liver to a complete stranger in the long run this would not be the best idea. By offering payment for organ donation the system would wind up having a sperm bank like effect in which there would be an influx of people coming down to donate solely because they are in need of cash. Although more organs being donated is a good thing, like as with sperm banks individuals who have no business donating will more than likely try and get into the program so that they can get paid. Though all donors would be tested before they could donate, increasing the number of unhealthy donors who sign up to donate increases the chance that something might be missed and wind up infected the organ recipient. This is especially dangerous since it takes time for some illnesses/viruses to be detectable, such as H.I.V. which can take approximately one - three months before it generally will be detected by an antibody test.<sup>40</sup>

Finally, we do not want to push the concept of people selling organs for cash. Although it would still be illegal to do so we do not want to take the chance that more people will start thinking about going down to Mexico or some other country to try and find a shady doctor to remove a kidney or a piece of their liver so that it can be implanted into someone who is paying them for it because they do not want to wait for a legal organ transplant.

---

<sup>40</sup> “Most people develop detectable HIV antibodies within 6 to 12 weeks of infection. In very rare cases, it can take up to 6 months.” AVERT, *The Different Types of HIV Tests*, <http://www.avert.org/testing.htm>

## ***MEDICAL ASSURANCE UNDER LIVING DONOR PROGRAM***

Under the current system that we have in place in terms of organ donors living donors take up more than just the risk of being injured in the surgery. When people decide to become a living organ donor they also wind up putting themselves at risk financially, and though there are some policies and practices in effect that help to remove some financial burden from the living donor, in the long run a persons decision to donate an organ prior to their death could wind up causing them an arm and a leg later on in life.

The way organ donation currently works is that initially all the costs are put onto the recipient and are billed to their insurance company. Thus the hospital bills for the initial tests to see if the donor is a match, whether he or she is even eligible to donate the specific organ, and "acquisition fee"<sup>41</sup> for the actual surgery in which they remove the organ from the donor are all taken care of by the insurance of the person receiving the organ, leaving the donor without an bills in the beginning other than possibly the cost of getting to the city and hospital in which all of these things are taking place. Additionally, "the medical costs related to the donation procedure and required postoperative care are also covered by this fee".<sup>42</sup>

Although the initial costs for organ donation are taken care of by either the recipient's insurance provider, or in some circumstances by the Transplant Centers Organ Acquisition Fund. These things only cover the cost for the actual donation and the recovery from the surgery to remove the organ, they do not extend out to help the donor in the event that their decision to donate the organ causes illness later on. For example, if

---

<sup>41</sup> UNOS, *Financial Aspects: Living Donation Costs*,  
<http://transplantliving.org/livingdonation/financialaspects/costs.aspx>

<sup>42</sup> *Id*

someone were to become a living kidney donor and then later on in life something happens and the one kidney that they have left starts to fail then the original donor and their insurance provider would bare the burden of dealing with the costs of getting treatment or a kidney transplant. Things that they may not have had to of dealt with if they had not donated their other kidney earlier on in life. Although it could be possible that the person could have had kidney failure in both their kidneys there are many people who have kidney failure in only one kidney and there is not much of a problem because they can continue on with just the other kidney.

Although just like with the original donee if someone became in need of an organ transplant as a result of an organ donation that they made earlier in their life their insurance would help take care of the costs this does not save the original donor from being financially burdened by their decision to become a living organ donor. If the person does not have any insurance at the time they become sick then the there is no one to help with the costs of the medical care and unless the person becomes one of the lucky people whose care and surgery are paid for out of the Transplant Centers Organ Acquisition Fund then they will have to foot the very expensive hospital/ doctors bill all because at some point earlier in their life they decided to be a good citizen.

As for people who do have insurance, although the insurance company will pay most of the costs there will still be a financial burden on the person because insurance companies charge higher rates for people who have donated organs in the past.<sup>43</sup> The reasoning behind the higher health insurance rates is because people who have donated organs are at a higher risk of becoming ill as a direct result of their prior organ

---

<sup>43</sup> AJC, *System Punishes Organ Donors*, <http://www.ajc.com/opinion/system-punishes-organ-donors-189025.html>

donation.<sup>44</sup> Since there are numerous health risks that the donors face after giving an organ insurance companies help protect themselves by charging the donor more for their insurance, although this is not something that insurance companies should be blamed for doing it is something that we should try and fix. The whole point behind the insurance business is that insurance companies are paid in order to relieve individuals of the stress behind paying large amounts for hospital bills if they get sick, in return for the huge financial risk the companies take on for each and every one of their clients the insurance companies get to profit off the premiums of those who pay into the policy but never need to collect on the more expensive services of the insurance company. The general concept behind insurance companies is a good one if you live in a society in which you have to pay for health care and the prices for even what are considered relatively small procedures can wipe out someone's entire savings or even make them go bankrupt. Additionally, it is understandable that for people who pose and even higher risk of the insurance company having to pay a hefty load in medical fees that they charge a higher insurance premium, otherwise if an insurance company decided to charge the same for everyone no matter the level of risk, unless this standard rate was extremely high, all the

---

<sup>44</sup> There are many long-term organ specific complications/risks for people who were living organ donors. Kidney donors face the risk of Hypertension, Kidney Failure, and Proteinuria; Lung donors face the risk of Intra-operative ventricular fibrillation arrest, Postoperative pulmonary artery thrombosis, Bronchopleural fistula, Pleural effusion, Empyema, Bronchial stricture, Pericarditis, Arrhythmias, Chylothorax, Pneumothorax, Hemoptysis, and Dyspnea; Liver donors face the risk of Bile leakage, Hyperbilirubinemia, Small bowel obstruction, Biliary stricture, Portal vein thrombosis, Pulmonary embolism, Intra abdominal bleeding, Pancreatitis, Bleeding duodenal ulcer, Renal failure, Gastric perforation, Gastric outlet obstruction, and Pleural effusion; Pancreas donors face the risk of Diabetes, Splenectomy, and Pancreatitis; and Intestine donors face the risk of Short bowel syndrome, Small bowel obstruction, Dysvitaminosis, Weight loss, and Diarrhea. Transplant Living, *Risks and Potential Complications*, <http://transplantliving.org/livingdonation/outcomes/risks.aspx>

high risk patients would switch to that company possibly causing them to hemorrhage money due to all the procedures they would wind up paying for.

Though it is understandable to see why an insurance company would raise the rates for people who donated an organ and thus became a higher risk client than they were before it is not as clear as to why we let people who donate organs to be put in the position in which they have to worry about paying for the costs of medical needs due to their organ donation. If things were changed to insure that people who donated organs would not have to worry about this it would make things a lot easier and could in fact help slightly increase the number of people willing to donate certain organs to people they know since they would not have to worry about the financial repercussions in their decision making process when deciding whether to donate.

Recent legislation has provided some relief by allowing for grant money to be allocated towards helping take care of some of the travel and subsistence expenses of people who decide to become living donors but this is just short term financial relief, something that could and should be fixed.<sup>45</sup>

### ***LEGAL AUTHORITY BEHIND SYSTEM APPLICATION***

In order to try to put a system such as this in place the FDA could draw upon the legal authority provided by 42 U.S.C.S. § 264, “Regulations to control communicable diseases”, which states that “The Surgeon General, with the approval of the Administrator [Secretary], is authorized to make and enforce such regulations as in his

---

<sup>45</sup> The Organ Donation and Recovery Improvement Act gives the Secretary the ability to give grants to “States, transplant centers, qualified organ procurement organizations under section 371, or other public or private entities” to be used to reimburse living organ donors for travel and subsistence expenses made towards their organ donation. The Organ Donation and Recovery Improvement Act, Pub L. 108-216

judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.”<sup>46</sup> This is the same legal authority they drew upon in the 1990’s in order to regulate tissues.

This would incorporate the vast majority of the system because all the various aspects could arguably be stated to be for the purpose of stopping the spread of infectious diseases. The database in itself is for the sole purpose of keeping track of people’s health in order to ensure infectious organs do not get transplanted into healthy individuals or at least individuals who do not have that specific infectious disease. Additionally, the general purpose behind both of the donor programs would also be in part for the purpose of stopping the spread of infectious disease because they are set up in order to get more healthy people to make the decision to become organ and tissue donors so that the overall risk of transferring an infectious disease through transplantations is lowered.

## **V. POSSIBLE ISSUES WITH MODEL SYSTEM**

With the implementation of a new system it would undoubtedly be protested by people due to reasons such as fear and genuine disagreement with the system altogether. With the aforementioned proposed system there are various reasons why people might possibly be weary or angered by its introduction, some possibly being valid and many probably being “eccentric”.

---

<sup>46</sup> 42 U.S.C.S. § 264 (a)

## ***POSSIBLE FEARS***

One possible fear that people may have is that paying people to be postmortem donors may result in people participating in the program who shouldn't all because they wanted to make easy money and could thus cause the same result that the system was trying to avoid by not paying people to become living organ donors; an increased risk of harmful organs being transplanted into a patient.

Another possible fear that this system could cause is that some people might think that by the government having their information and fingerprints on file it would be easier for people to be set up for crimes that they did not commit. The logic behind this would probably be that since peoples fingerprints will be on file then they could possibly be planted at crime scenes.

Although this may seem like something more so from a horror movie another possible fear that people could bring forth concern about could be the issue of people taking advantage of this new system by starting to take out people who are organ donors in order to either receive the benefit from them being an organ donor or in order to get the organs out onto the market sooner.

Like one should do with any negative emotions surrounding the introduction of something new into people lives it would be important that people's fears were addressed. In regards to the fear that the postmortem system could cause an increase in risky people becoming organ donors the whole purpose of the 6 month check ups is to make sure that the participants' health is being maintained and that they would still be viable candidates for post mortem organ extraction. Since this program is for people who are willing to donate their organs after they die the hopes are that these people will live



for a good deal of time unless an accident occurs. The longer individuals in this program live the easier it is to see who lives what type of lifestyle and those whose lifestyle pose a threat and cause their organs to be unhealthy would be removed from the program.

Additionally, even though participants will have routine health screenings on the event of their demise they would still be tested for disease. Finally, unlike people who would sign up to be a living donor for money, people who participate in a postmortem donor program for money would be more likely to try and avoid things that could put them at a great risk of contracting something because it would stop the in flow of cash from the program.

In regards to the fear of making peoples fingerprints available there would be some privacy in that the database would be for the purposes of maintaining information for health purposes only and would not be shared with general law enforcement agencies. Additionally, if technology is at the point in which you can use a scanned image and use that to make a phony fingerprint to plant at a crime scene than finger prints probably would not be as incriminating as they are today because of the ease in manipulating them at crime scenes. Additionally, since it is already not that hard to pull a real fingerprint off of something the need for the technology to build a phony fingerprint from a scan would not be needed to set someone up.

In terms of the pushing organs faster scenario though, although the U.N.O.S list may not be highly publicized even with the system that is in play today technically someone with money at the top of the transplant list could hire someone to take out people who have signed the back of their drivers licenses to be an organ donor in order to get more organs flowing in to take care of the people at the top of the U.N.O.S. list.

Technically what is probably the safest thing for someone who is afraid that they may be taken out in order to get more organs for U.N.O.S patients is more people signing up to be organ donors when they pass away. With the number of people who die everyday if more and more people signed up to be an organ donor the time each patient would spend on the waitlist would drop, thus making the need to send someone to help speed the process up would not be as necessary.

### ***RIGHT TO PRIVACY ISSUE***

Some people may feel that the creation of a national database in which everyone's medical records are kept would take away peoples rights to privacy because they would not have a say in whether or not their information was kept in the file, even if they did not plan to donate any organs.

Unlike with simple medical files, in which you would have to know who you are looking for the creation of a database with everyone's information makes it possible for people with access to look up groups of people with specific illnesses with a quick search and have a list of individuals almost instantaneously. Thus people's personal information would be available to individuals who do not even know the patient but simply were looking into people with a particular illness. This could anger individuals because they could possibly be affected if lists of diseased individuals made their way out into the public. This has been an issue for numerous groups who have contracted infectious diseases because of the fear of what the public would do if lists got out. In the past this especially was an issue with people who had contracted H.I.V.

Although some people may not choose themselves to become organ donors the ability to still have information about them on file is important because there are

instances in which the families of deceased individuals, upon their deaths, make the decision to donate the persons organs so that they could be transplanted into someone alive who is in need of a new organ. It is because of instances like this that having background eligibility information on everyone becomes important.

Additionally, the ability to record information on everyone would help allow for the program to evolve as time progresses. For example, having knowledge on everyone who has H.I.V. could help make it possible to expand the system so that people with H.I.V. who are the waitlist for a new organ can get a transplant from a deceased donor who was also infected with H.I.V. thus providing more transplantable organs into the overall mix.

Finally, the government keeping tabs on people with certain illnesses is not a new thing. In fact it is already being done to an extent with individuals who are living with H.I.V. or A.I.D.S. In 2006 the federal government introduced the Ryan White HIV/AIDS Treatment Modernization Act of 2006 part of the act set up grants for states in which the formula for determining the grants was based upon the number of “names-based” cases were reported to the CDC.<sup>47</sup> Although the program may not be in full effect with the names of everyone who have been diagnosed with H.I.V. or full blown A.I.D.S. most of the states have been participating in this program since early 2007.

---

<sup>47</sup> “Except as provided in clause (ii), the number determined under this subparagraph for an eligible area for a fiscal year for purposes of subparagraph (B) is the number of living names-based cases of HIV/AIDS that, as of December 31 of the most recent calendar year for which such data is available, have been reported to and confirmed by the Director of the Centers for Disease Control and Prevention.”

109 P.L. 415 § 102 (b) (2) (C) (i)

## VI. CONCLUSION

While we wait for scientist to finish with the work towards the ability to grow organs to transplant into individuals and erase the need for organ donors the creation of a new effective system for organ and tissue transplants could drastically make a difference in the United States. By implementing a system in which a deceased person's vital medical information could easily be accessed to help with the decision behind whether their organs could and should be transplanted into someone money could be saved on pointless tests on the organs of people who would have been ruled out from organ donation for a while and lives could possibly be saved.

Additionally by increasing the number of people who sign up to be organ donors we would have the possibility to vastly shorten the waiting time and list for organ transplants. Over 107,000 people are currently on the UNOS waitlist waiting to be provided with an organ<sup>48</sup> and every day approximately 19 people on this waitlist die because they were unable to get an organ transplant.<sup>49</sup> Approximately every 16 minutes a suicide takes place resulting to on average about 89 suicides per day.<sup>50</sup> Each day there about 4.5 times as many people die from suicide alone than there are people who die in need of an organ transplant yet the waitlists for organ transplants are still so high.

In order to fix the problems in our current system and also help make it so that current medical research can continue on smoothly and not have to worry about

---

<sup>48</sup> OrganDonor.Gov, *Waitlist Candidates*, <http://www.organdonor.gov/>

<sup>49</sup> Richmond Times Dispatch, *UNOS Plays National Role In Lifesaving Organ Transplants*, (March 22, 2009) [http://www2.timesdispatch.com/rtd/news/opinion/commentary/article/GRAHAM322\\_20090320-202112/237209/](http://www2.timesdispatch.com/rtd/news/opinion/commentary/article/GRAHAM322_20090320-202112/237209/)

<sup>50</sup> American Foundation For Suicide Prevention, *Quick Fact For Suicide Prevention*, [http://www.spanusa.org/index.cfm?fuseaction=home.viewPage&page\\_id=0D213AD4-C50A-1085-4DD96CE0EEED52A0](http://www.spanusa.org/index.cfm?fuseaction=home.viewPage&page_id=0D213AD4-C50A-1085-4DD96CE0EEED52A0)

regulatory battles slowing things down the FDA should take the regulatory power over organs that they should have had all along.

Although efforts are technically being made to try and address the issues that arise from this split as long as the split in regulatory powers remain the efforts will never be enough. Take the FDA rule 21 CFR 1271 (also known as HRSA 42 CFR Part 121) that deals with blood vessels that are recovered with organs and are intended to be used in organ transplants. This was issued in order to fix the burden caused due to separate regulations towards blood vessels as a part of an organ transplant and then there are for ones that are not. Although this rule may have slightly cleared things up for instances in which the vessels are extracted with an organ for solely organ donation purposes the issue still remains about what is to be done about blood vessels that are removed alongside organs and tissues from a deceased donor all of which are for transplant purposes. Are only the vessels that were attached to the organ supposed to be deemed for organ transplant purposes? Are all the vessels going to be deemed for this purpose and none for transplant purposes on their own? Are they supposed to split the amount so some are set aside for one use and some for the other? And how would it be addressed if they are set deemed to be for one purpose but it then turns out they were not really all needed for that purpose and are actually needed for the other purpose? As long as the split remains anything that is issued as a fix to the problem will just merely move the line over a little further in one direction or another but will never get rid of it.

In the end the conclusion is simple. The next joint issuing of a rule that the FDA and HSRA issue should be short simple and sweet “ As of (insert future 4 digit date here that hopefully starts with 201) the HRSA will no longer have regulatory control over

organs, all regulatory control for organs from this point forward will fall under the powers of the Food and Drug Administration, FDA”.